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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,923	10/27/2005	Alexander Pavlovich Sorokin	0380-P03628US0	6599

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/536,923

Applicant(s)

SOROKIN ET AL.

Examiner

Medina A. Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 25-32 is/are rejected.
- 7) ☐ Claim(s) 18-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-32 are pending and are examined.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Copending Applications

Applicants must bring to the attention of the Examiner, or other Office official involved with the examination of a particular application, information within their

Art Unit: 1638

knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

At claims 17-20, it is suggested that "A" be changed replaced with ---The--- because it refers to a previous claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 17 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing transgenic plants for phytoremediation comprising transforming the plant with the rh1A gene and/or rh1B gene and transgenic plants comprising said genes, does not reasonably provide enablement for a method that employs a nucleic acid from any source encoding an enzyme having rhamnosyltransferase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the CAFC considered a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples of the invention; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability or unpredictability of the art; (g) the breadth of the claims; and (h) the relative skill in the art.

The claims are broadly drawn to a method of phytoremediating an environment which is contaminated with at least one heavy metal or oil hydrocarbon by providing a transgenic plant expressing at least one nucleic acid encoding an enzyme having rhamnosyltransferase activity, and planting said plant in said environment. The claims are also drawn to said method wherein the environment is contaminated with both heavy metal and oil hydrocarbon pollutant, and wherein the enzyme is involved in the synthesis of monorhamnolipids. The claims are further drawn to transgenic plants expressing said at least one enzyme.

Applicant teaches transformation of tobacco and Arabidopsis with the *Pseudomonas aeruginosa* rh1A gene, rh1B gene or both, transformed tobacco and Arabidopsis plants expressing said enzymes, and methods of using transgenic plants to remove copper and crude oil hydrocarbon contaminants from copper and crude oil hydrocarbon contaminated soil (Examples 1-6 and Tables 1-2).

The specification does not provide sufficient guidance for a method that employs

Art Unit: 1638

other than *Pseudomonas aeruginosa* rh1A and rh1B genes for the transformation of plants for phytoremediation of heavy metals and oil hydrocarbons soil contaminants.

The specification does not provide guidance regarding all nucleic acids encoding enzymes having rhamnosyltransferase activity or their ability to induce heavy metal and hydrocarbon tolerance activity upon expression in transgenic plants.

The mechanism of heavy metal accumulation in plants is complex and yet to be elucidated. See Hofgen et al (Amino Acids (2001) 20:291-299).

The state of the prior art is that the ability of a plant to accumulate heavy metals is a genotype dependent and varies greatly between species and between cultivars within the species (Salt et al Biotechnology, vol. 13, pp. 468-474, 1995). Guerinot et al (Plant Physiology (2001), vol. 125, pp. 164-167) suggest that it is unlikely that the regulation of a single gene will be sufficient to convert non-metal tolerant/accumulating plants into metal tolerant/accumulator plants. Peter Goldbrough (Ann Arbor Press, pp. 221-228, 1999) discloses transformed Arabidopsis plants that didn't provide increased heavy metal accumulation as compared to control plants. Goldsbrough reports "while ECS could restore some degree of Cd tolerance to a Cd-sensitive mutant (a cad2 mutant having reduced GSH levels), this gene didn't increase Cd tolerance of wild-type plants (page 230, 1st and 2nd full paragraphs).

One skilled in the art would have to proceed with trial and error experimentation to practice the full scope of the claimed invention in view of the lack of guidance in the specification or the prior art with regard to the identification of nucleic acids other than the rh1A and rh1B genes required for the claimed methods and transgenic plants for

Art Unit: 1638

phytoremediation, and unpredictability inherent in genetically modifying plants for phytoremediation. One would not reasonably be able to extrapolate Applicant's results with *Pseudomonas aeruginosa* rh1A and rh1B genes to all nucleic acids encoding enzymes having rhamnosyltransferase activity including all involved in the synthesis of monorhamnolipids, absent further guidance.

Therefore, given the breadth of the claims; the lack of guidance; the limited working example; the unpredictability in the art; the state of the art; the level of skill in the art; and the nature of the invention as discussed above, the claimed invention is not enabled throughout the broad scope. See *in re Fischer*, 166 USPQ 19 24 (CCPA 1970) where the court required that the scope of the claims must bear a reasonable correlation with the scope of the enablement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gressel et al (WO 00/43490, Applicant's IDS).

The Claims are drawn to a vector comprising at least one nucleic acid encoding an enzyme having rhamnosyltransferase activity and transgenic plants including tobacco transformed with said vector.

Gressel et al teach a plant transformation vector comprising a nucleic acid

Art Unit: 1638

encoding an enzyme having rhamnosyltransferase activity and transformation of plant cells and plants including tobacco plants with said vector (see pages 19-20). Therefore, Gressel et al teach all claim limitations.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

1/19/07

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MEDINA A. IBRAHIM
PRIMARY EXAMINER

